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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,443	08/16/2006	John J. Kopchick		7248

7590 04/02/2008

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EXAMINER	
GAMETT, DANIEL C	
ART UNIT	PAPER NUMBER
1647	
MAIL DATE	DELIVERY MODE
04/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,443	KOPCHICK ET AL.	
	Examiner	Art Unit	
	DANIEL C. GAMETT	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10 and 11* is/are rejected.

7)☒ Claim(s) *7-9 and 12-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-21 are under consideration.

Claim Objections

2. Claims 7-9 and 12-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall not depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 7-9 and 12-21 have not been further treated on the merits.

3. The remainder of this office action is directed to claims 1-6, 10 and 11.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 10 and 11are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

6. The fact that a patent is directed to method entailing use of a compound, rather than to the compound *per se*, does not remove patentee's obligation to provide description of the compound sufficient to distinguish infringing methods from noninfringing methods (University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CAFC 2004)). In this case, claims 1 is drawn to a method that comprise administration of a genus of compounds recited as "(1) a polypeptide which is substantially structurally identical or conservatively identical in sequence to a reference protein which is (a) selected from the group consisting of mouse and human proteins set forth in master table 1, subtables 1A and 1C, or (b) selected from the group consisting of human proteins within at least one of the human protein classes set forth in master table 2, subtables 2A and 2C, or (2) an expression vector encoding the polypeptide of (1)." Claim 2 recites the same goal as claim 1, but recites administration of "(1) an antagonist of a polypeptide, occurring in said subject, which is substantially structurally identical or conservatively identical in sequence to a reference protein which is (a) selected from the group consisting of mouse and human proteins set forth in master table 1, subtable 1B and 1C, or (b) selected from the group consisting of human proteins belonging to at least one of the human protein classes set forth in master table 2, subtables 2B and 2C, (2) an anti-sense vector which inhibits expression of said polypeptide". Claims 3, 4-6, 10, and 11 are drawn to screening methods that require the skilled artisan to detect expression of similarly defined sequences from Tables 1 and 2.

7. The claims recite "a reference protein". Tables 1 and 2 provide lengthy lists of gene sequences identified by name and accession numbers. Full knowledge of these reference proteins is essential for the written description of the claimed subject matter. The attempt to incorporate

subject matter into this application by reference to accession numbers, as in Tables 1and 2, is ineffective because it is not in compliance with 37 CFR 1.57(c): "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. "Essential material" is material that is necessary to: (1) Provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C." In accordance with MPEP 2163.07(b) information incorporated by reference "is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter." Therefore, it may be possible to add the identified sequences in a manner that conforms to the sequence rules (see MPEP 2421). However, it is recognized that databases are subject to revision. An attempt to add sequences that deviate from the identified sequences as they were known at the time the instant application was filed would constitute new matter. See 37 CFR 1.57 (c-g).

8. Even if the reference proteins were properly disclosed in the specification, the claims recite a genus, ""substantially structurally identical or conservatively identical in sequence to a reference protein". To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be

considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The specification indicates that "substantially identical" may include polypeptides with as little as 50% identity to the reference protein ([0150] in the published application). Thus, the genus "substantially structurally identical or conservatively identical in sequence to a reference protein" is only identifiable by a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Of course this would be impossible because no individual protein listed on the tables is identified to possess the recited activity of protecting a subject from disease progression or indicating a propensity to progress from a normoinsulinemic state to a hyperinsulinemic state. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of this claimed genus.

9. Even if the genus of polypeptides were described, the genus of "antagonist of a peptide" (claim 2) is described only by a proposed function, with no structural definition. Again, the function with relation to disease progression is not defined for any specific protein, so the proposed function of "antagonist" provides no description at all for the molecule being claimed. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of this claimed genus.

10. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry,

whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Possession may not be shown by merely describing how to obtain possession of members of the claimed genus or how to identify their common structural features. See *University of Rochester*, 358 F.3d at 927, 69 USPQ2d at 1895. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

11. Claims 1-6, 10 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

12. The courts have interpreted the first paragraph of 35 U.S.C. 112 to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been

described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

a. *The nature of the invention:* The invention is complex, as it purports to provide a means for identifying human subjects who have a propensity for progression from a normoinsulinemic state to a hyperinsulinemic state, and novel means to intervene in that progression. The invention relies on the premises that genes identified by differential display analysis of control, hyperinsulinemic, and diabetic mice are *each* correlated with disease progression, so as to enable screening by measuring expression of any single gene, and that *each* identified gene product has a functional role in disease progression such that its activity or expression can be regulated with therapeutic benefit.

b. *The breadth of the claims:* The intervention method is claimed to be performed by administration of any one of hundreds of different polypeptides, and polypeptides "substantially structurally identical or conservatively identical" thereto, an expression vector encoding any of said polypeptides, or any anti-sense vector that would inhibit expression of any of said polypeptides, or any one of a genus of as yet unidentified "antagonists" of any one of said polypeptides. The identification of human subjects who have a propensity for disease progression is recited to be accomplished by measuring the

expression of any one of said polypeptides, or its encoding mRNA, in any tissue or body fluid.

c. The state of the prior art and the predictability or lack thereof in the art: Diabetes mellitus is a pleiotropic disease of great complexity and multiple environmental and genetic factors are involved in the development of insulin resistance, hyperinsulinemia and type II diabetes (see instant published specification at [0008] and [0016]). Known methods of slowing disease progression and/or treating type II diabetes include, for example, alteration in diet, increasing the amount of exercise, (i.e. preventing obesity) and drug treatment, including insulin and drugs to stimulate insulin secretion.

d. The art recognizes that the mere finding by differential display analysis that a given gene is differentially expressed in diseased subjects does not allow one to conclude that the said gene is actually either diagnostic or a target of a therapeutic treatment. For example, Corominola *et al.,* Diabetes, **50,** 2822-30, 2001, performed differential display analysis of tissues from lean, obese non-diabetic, and obese type II diabetic humans and found that out of 28 candidate genes identified by differential display only 3 (10.7%) could be confirmed to be actually differentially expressed in patients (see table 4 and chapter "Confirmation.. . " on p. 2826-27). Thus differential display, by itself, cannot support any predictions that any individual gene or protein could be a diagnostic or therapeutic target.

e. The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). The claims point to

the lack of guidance in the instant specification. Claims 1 and 2 are drawn to methods of protecting a human subject from progression from a normoinsulinemic state to a hyperinsulinemic state. According to claim 1, polypeptides from subtables 1C and 2C can be used for protecting a human subject from progression from a normoinsulinemic state to a hyperinsulinemic state. According to claim 2, *antagonists* of these same polypeptides are recited to be used to achieve the same effect. The specification provides no sound explanation or example of how administration of either a polypeptide or an antagonist to the same polypeptide could result in the same beneficial effect in a patient. This logical contradiction is repeated in claims 3 and 4, wherein subtables 1C and 2C are recited to contain both "favorable" and "unfavorable" genes, the expression of which is asserted to either directly (claim 3) or inversely (claim 4) correlate with propensity for progression from a normoinsulinemic state to a hyperinsulinemic state. It is impossible for any single polypeptide to be both directly and inversely correlated with disease progression. The contradictory recitations, and the data underlying the inclusion of genes in mutually exclusive mechanistic categories, shows that these genes have no discernable role in disease progression. Therefore, one cannot predict whether administering any of these proteins or antagonizing their expression or activity will have any beneficial effect. Likewise, it cannot be said the measurement of their expression would be at all informative with respect to hyperinsulinemia or diabetes. Thus, the claims and the specification negate any possibility of enablement for the claimed methods with any polypeptide listed on subtables 1C and 2C.

f. The specification sets forth confusing and contradictory definitions for "favorable" and "unfavorable". These detract from the guidance provided by the specification and are at odds with the claims:

[0043] Thus, "favorable" human genes/proteins are defined as those corresponding to mouse genes which were less strongly expressed in mouse hyperinsulinemic liver than in control liver, or less strongly expressed in mouse type II diabetic liver than in hyperinsulinemic liver. (The control liver is the liver of a mouse which is normal vis-a-vis fasting insulin and fasting glucose levels. The term "normal", as used herein, means normal relative to those parameters, and does not necessitate that the mouse be normal in every respect.) Likewise, one may define "unfavorable" human genes/proteins as those corresponding to mouse genes which were more strongly expressed in mouse hyperinsulinemic liver than in control liver, or more strongly expressed in mouse type II diabetic liver than in hyperinsulinemic liver.

[0417] There are three possible comparisons, HI-D, C-HI, and C-D, where C=control (normal), HI=hyperinsulinemic, and D=diabetic. [0421] If the level of the gene in the former state is at least two-fold that in the latter state, it is considered unfavorable. If the level of the gene in the former state is not more than half (i.e., not more than negative two fold) that in the latter state, it is considered favorable.

Thus, in [0043] "favorable" genes are less highly expressed in the disease state, i.e. they are *inversely* correlated with disease. "Unfavorable" genes are more highly expressed in the disease state, i.e. they are *directly* correlated with disease. Precisely the opposite is recited in claim 3 and 4. In contrast, [0417] indicates that, for example, a gene that is expressed more highly in control than hyperinsulinemic animals, is "unfavorable". The expression of such a gene is inversely correlated with disease, which agrees with claims 3 and 4. Apparently "favorable" and "unfavorable" mean different things in different places. In [0043], a "favorable" gene is favorable to the health of the patient. In [0417], and apparently in claim 3, a "favorable" gene favors the progression of disease. The

claims recite the tables. The contents of the tables are determined according to [0417]. It therefore appears that [0043] is errant, and its misdirecting teaching regarding "favorable" and "unfavorable" should be ignored. Section [0043], does indicate that the scope of "assaying a body tissue or body fluid" is not enabled; the genes are identified on the basis of expression in the liver. This is confirmed in [0434].

g. The designations of "favorable" and "unfavorable" appear to ignore mechanisms of action and lead to logical contradictions in the claimed methods. A given protein might contribute to disease either by being overexpressed (or overactive) or by loss of a necessary function required to maintain health. Consider a hypothetical protein, P, which has a normal level of expression, but when overexpressed contributes to disease. Protein P would logically be "unfavorable" to health, but according to [0417] it would score as "favorable", and it would be listed in Table 1A. Its high level expression would be considered indicative of disease in claim 3 (this makes sense) but claim 1 would have this protein (or its gene) administered to raise its activity in order to *protect a subject from disease progression*. This doesn't make sense. Conversely hypothetical protein Q, for which loss of its normal expression contributes with disease, would score as "unfavorable"; it would be listed in Table 1B. Its expression would be inversely correlated with disease (claim 4) but the method of claim 2 would have Q's activity or expression further antagonized, when logically a goal of therapy would be to restore its activity.

h. From the analysis above, it can be seen that the screening methods of claims 3 and 4 are logically consistent with the definitions in [0417] but the treatment methods in claims 1 and 2 are not. Consequently, claims 1 and 2 totally lack enablement because the guidance in the specification indicates that they will not work.

i. According to Claim 3, for example, one should be able to select *any gene* from Table 1A, measure its expression of its *mRNA or protein* in a subject, and conclude that the subject has a propensity for progression from a normoinsulinemic state. This conclusion is based upon an alleged direct correlation between the genes of Table 1A and disease progression. Similarly, claim 4 relies on an alleged inverse correlation between the genes of Table 1B and disease progression. No such correlations are established in the instant specification. As noted, differential display is useful for screening but its confirmation rate when compared to other methods of mRNA detection is quite low, (Corominola *et al.,* Diabetes, **50,** 2822-30,2001, cited above). Furthermore, even if mRNA expression is elevated, it does not follow that the corresponding protein level is also elevated. Greenbaum *et al.* (Genome Biology, 2003, Vol. 4, Issue 9, pages 117.1-117.8) cautions against assuming that mRNA levels are generally correlative of protein levels. The reference teaches (page 117.3, 2nd column) that primarily because of a limited ability to measure protein abundances, researchers have tried to find correlations between mRNA and the limited protein expression data, in the hope that they could determine protein abundance levels from the more copious and technically easier mRNA experiments. To date, however, there have been only a handful of efforts to find correlations between mRNA and protein expression levels, most notably in human

cancers and yeast cells. And, for the most part, they have reported only minimal and/or limited correlations. The reference further teaches (page 117.4, 2nd column) that there are presumably at least three reasons for the poor correlations generally reported in the literature between the level of mRNA and the level of protein, and these may not be mutually exclusive. First, there are many complicated and varied post-transcriptional mechanisms involved in turning mRNA into protein that are not yet sufficiently well defined to be able to compute protein concentrations from mRNA; second, proteins may differ substantially in their *in vivo* half lives; and/or third, there is a significant amount of error and noise in both protein and mRNA experiments that limit our ability to get a clear picture. The reference further notes (page 117.6, page 2nd column) that to be fully able to understand the relationship between mRNA and protein abundances, the dynamic processes involved in protein synthesis and degradation have to be better understood. Therefore, the art indicates that it is not the norm that increased transcription results in increased polypeptide levels. It is also clear that a *2-fold* difference in transcript levels ([0147] of the instant published application) is not reliably predictive of any difference in protein levels.

j. The data disclosed in Tables 1 and 2 do not justify any assertion that any single gene or protein is a diagnostic marker or a therapeutic target, as recited in the instant claims. Such an assertion could only be supported by direct evidence for a specific recited gene or gene product.

k. *The quantity of experimentation needed:* It is not clear that the recited methods will ever work regardless of how much experimentation a skilled artisan might be willing

to perform. There may be a diagnostic marker or a therapeutic target somewhere in Tables 1 and 2, but this specification does not identify it. The courts have stated that patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may not be workable. Tossing out the mere germ of an idea does not constitute an enabling disclosure. Reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. See *Genentech v. Novo Nordisk A/S* (CAFC) 42 USPQ2d 1001 (1997).

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 recites the limitation "reference protein is of subtable 1B or of a class set forth in subtable 2B" in claims 1 or 3. There is insufficient antecedent basis for this limitation in the claim. Claims 1 and 3 do not recite tables 1B or 2B.

15. Claims 3-6, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The skilled artisan, upon reading the recitation of "favorable" and "unfavorable" marker genes in claim 3 and 4, would look to the specification to determine the metes and bounds of these terms. As noted in the rejection under 35 U.S.C. 112, 1st paragraph above, the instant specification sets forth confusing and contradictory definitions for "favorable" and "unfavorable". It was also noted that, upon close inspection, one can conclude that the

definition found in [0417] is controlling and that the one at [0043] should be ignored. However, a requirement for such analysis is hardly consistent with "particularly point out and distinctly claim". This could be obviated by removal of these terms from the claims. They are not needed, as evidenced by claims 1 and 2.

16. Claims 1-6, 10, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims depend on the contents of Tables 1 and 2 to inform the skilled artisan as the metes and bounds of the claims. It is recognized that databases are subject to revision. In the absence of recitation of a dated version of each accession number, the metes and bounds of the claimed subject matter cannot be determined. Therefore, the actual sequences are essential to satisfy the requirements of 35 U.S.C. 112, second paragraph. The attempt to incorporate subject matter into this application by reference to accession numbers, as in Tables 1 and 2, is ineffective because it is not in compliance with 37 CFR 1.57(c): "Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference. **"Essential material" is material that is necessary to: (2) Describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112.** In accordance with MPEP 2163.07(b) "the information incorporated is as much a part of he application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the

identified material incorporated by reference with the actual text is not new matter." Therefore, it may be possible to add the identified sequences in a manner that conforms to the sequence rules (see MPEP 2421). Applicant is cautioned against introduction of new matter by attempting to add sequences that deviate from the identified sequences as they were known at the time the instant application was filed. See 37 CFR 1.57 (c-g).

Conclusion

17. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD., whose telephone number is (571)272-1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel C Gamett/
Examiner, Art Unit 1647